

REMARKS

In the Office Action, the Examiner objected to the form of the abstract. Claims 15-22 were also objected to as making an improper reference to the phrase “the kit of claim 11”, when claim 11 was directed to a method, not a kit. Further, claims 1, 5, 6, 9-14, 18, 19, 21 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Thieme (USPN 5,871,905) in view of Doneen (USPN 6,102,872). The remaining claims were also rejected under 35 U.S.C. §103(a) as being unpatentable over Thieme in view of Doneen, and in further view of Goldstein (USPN 5,335,673), D’Angelo (USPN 5,910,122) or Putcha (USPN 6,133,036).

Objections

Regarding the objections, claims 15-22 have been amended to proper refer to the “The method of claim 11”. The abstract has also been amended to clarify the scope and content of the invention and the application. Therefore, Applicant respectfully requests the withdrawal of the objections to the abstract and claims 15-22.

Rejections

35 U.S.C. §103

The references cited by the Examiner do not teach or suggest the use of a saliva collection device that has suction means and an exterior surface and wherein a salivation catalyst is positioned on the exterior surface of the collection device.

In rejecting claims under 35 U.S.C. §103, an Examiner bears the initial burden of presenting a *prima facie* case of obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A *prima facie* case of obviousness is established by presenting evidence that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him or her to make the proposed

combination or other modification. See *In re Lintner*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Furthermore, the conclusion that the claimed subject matter is *prima facie* obvious must be supported by evidence as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Rejections based on §103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. An Examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. See *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 177 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The Federal Circuit has repeatedly cautioned against employing hindsight by using the Applicant's disclosure as a blueprint to reconstruct the claimed invention from the isolated teachings of the prior art. See, e.g., *Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

When determining obviousness, "the [E]xaminer can satisfy the burden of showing obviousness of the combination 'only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002), citing *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). "Mere denials and conclusory statements, however, are not sufficient to

establish a genuine issue of material fact.” *Dembiczak*, 175 F.3d at 999-1000, 50 USPQ2d at 1617, citing *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993).

Further, as pointed out by the Federal Circuit, the Examiner must first determine the scope of the claim. “[T]he name of the game is the claim.” *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998).

In the Office Action, the Examiner cites to the following passage in Thieme as disclosing a saliva collection device:

In another embodiment, the oral fluid is stored and/or transported after collection. In one such preferred embodiment, the oral fluid is collected with the ORASURE® collection device (Epitope Inc., Beaverton, Oreg., USA). The collected oral fluid is placed in a storage vial containing a storage solution. The storage solution comprises a preservative.

See Thieme at column 11, lines 39-45.

However, Thieme and/or Doneen do not teach use of a saliva collection device that has suction means and an exterior surface and wherein a salivation catalyst is positioned on the exterior surface of the collection device. Therefore, one of skill in the art would not have looked to those references, or the combination thereof, to arrive at the claimed invention. More specifically neither Thieme nor Doneen disclosed the use of a suction means for the collection of saliva. The apparatus disclosed by Thieme at Figures 1A-3B is “a syringe or syringe-like device ... used to express the oral fluid from a collection sponge or absorbent pad.” Therefore, the syringe of Thieme was not used to actually collect a saliva sample and, accordingly, it would not have been obvious or even necessary to position a salivation catalyst on the exterior surface of the Thieme device. Furthermore, while Doneen may disclose the use of salivation catalyst in the

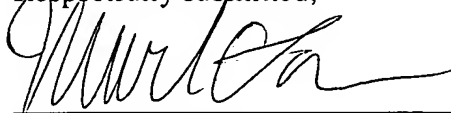
form of an osmotic substance 16, that catalyst must be totally enclosed by a semi-permeable membrane (see Doneen, column 4, lines 57-59). As such, to the extent that Doreen disclosed the use of a catalyst, that catalyst would not have been positioned on the exterior surface of the Thieme device or any other collection device.

Additionally, other references such as the '673 patent to Goldstein disclosed the use of a pad 3 on a stick 2. See Goldstein, column 6, lines 9-16. The pad 3 of Goldstein, however, is structurally and functionally different than a suction mean since such a pad must rely on *passive* absorption of a sample instead of the active collection of offered by a suction means.

Finally, even if it could be concluded that Thieme, Doneen, Goldstein or the other references cited by the Examiner taught the use of a suction means, none of those references also recite the use of a salivation catalyst is positioned on the exterior surface of that collection device.

In view of the above remarks, Applicant submits that the application is now in proper form for allowance. Such action is respectfully requested.

Respectfully submitted,



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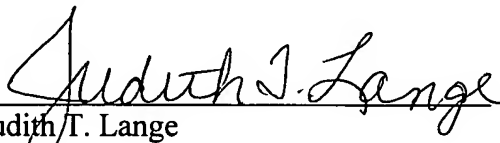


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